subject matter of Applicants' invention. Applicants' reserve the right to pursue claims as originally filed in this or a separate application.

Rejection of Claim 10 under 35 U.S.C. § 101

Claim 10 was rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of "prior U.S. Patent No. 9,800,832." As an initial matter, Applicants assume that this rejection contains a typographical error and that the Examiner intended to refer to U.S. Patent No. 5,800,832. If this is incorrect, please advise as to which U.S. patent is cited in this statutory double-patenting rejection. Assuming the statutory double-patenting rejection refers to U.S. Patent No. 5,800,832, Applicants respectfully traverse this rejection.

Claim 1 of U.S. Patent No. 5,800,832 recites:

> A bioerodable, water-soluble pharmaceutical carrier device comprising a layered film having a first water-soluble adhesive layer to be placed in contact with the mucosal surface and a second, water-soluble non-adhesive backing layer, and a pharmaceutical or combination of pharmaceuticals incorporated within said first or second layer wherein said first water-soluble adhesive layer comprises hydroxyethyl cellulose, polyacrylic acid, and sodium carboxymethyl cellulose; said second water-soluble non-adhesive backing layer comprises hydroxyethyl cellulose; and said pharmaceutical or combination of pharmaceuticals comprises dyclonine HCl.

Claim 10 of the instant application depends from claim 9, which in turn depends from claim 1. These pending claims read as follows:

> 1. A pharmaceutical carrier device comprising a layered flexible film having a first water-erodable adhesive layer to be placed in contact with a mucosal surface,and a second, water-erodable non-adhesive backing layer, wherein said device is capable of having a pharmaceutical incorporated within said first layer, said second layer, or both layers.
>
> 9. The pharmaceutical device of claim 1, wherein one or more of the layers further comprises a component which acts to adjust the kinetics of the erodability of the device.

10. The pharmaceutical device of claim 9 wherein the component is a water-based emulsion of polylactide, polyglycolide, lactide-glycolide copolymers, poly-ε-caprolactone and derivatives, polyorthoesters and derivatives, polyanhydrides and derivatives, ethyl cellulose, vinyl acetate, cellulose acetate, or polyisobutylene, alone or in combination.

The standard for determining whether a statutory basis for a double patenting rejection under 35 U.S.C. § 101 exists is whether the same invention is being claimed twice, wherein "same invention" means identical subject matter. M.P.E.P. 804-IIA. A reliable test for double patenting under 35 U.S.C. § 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim of the patent. M.P.E.P. 804-IIA; *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

In the instant case, claim 10 of the instant application is not claiming the "same invention" as claim 1 of the '832 patent, since claim 10 could be literally infringed without literally infringing claim 1 of the '832 patent. For example, claim 1 of the '832 patent recites that the "pharmaceutical or combination of pharmaceuticals comprises dyclonine HCl", whereas claim 10 does not. Thus, claim 10 could be literally infringed by a pharmaceutical device in which the pharmaceutical agent is a drug other than dyclonine HCl, whereas this would not literally infringe claim 1 of the '832 patent.

Thus, claim 10 of the instant invention and claim 1 of the '832 patent do not claim the "same invention" and the rejection of claim 10 for double-patenting under 35 U.S.C. § 101 is improper. Accordingly, Applicants respectfully request that this rejection be withdrawn.

Rejection of Claims under 35 U.S.C. § 102 (b)

The Examiner states that claims "6-6", 9, 10, 12-18 and 33 are rejected under 35 U.S.C. § 102 (b) as being anticipated by Suzuki et al. As an initial matter, Applicants assume that this rejection contains a typographical error and that the Examiner intended to refer to claims "1-6", 9, 10, 12-18 and 33. Moreover, since claim 11 is listed as being rejected on the cover sheet of

the office action, but is not otherwise referred to in the office action, Applicants also assume that claim 11 was intended to be included in this rejection. Accordingly, for the purposes of this response Applicants consider that this rejection applies to claims 1-6, 9-18 and 33 and request correction if this is incorrect. Applicants respectfully traverse this rejection and submit that it does not apply to the claims as currently pending.

The claims as currently pending are directed to a layered, *flexible* film having a first adhesive layer and a second, non-adhesive backing layer. In contrast, Suzuki et al. disclose multilayered tablets. Applicants refer the Examiner to the personal interview held January 10, 2000 with co-inventor D.W. Osborne and Applicants' representative (T. Ciotti) in parent application Serial No. 09/144,827. As described in the interview summary, during that interview "pills based on the prior art [Suzuki et al.] were compared to the film of the claimed invention." Agreement was reached, with the Examiner stating that "the Examiner will allow the case upon addition of language indicating flexibility." Since the claims of the instant application also recite the term "flexible", these claims also are distinguishable over the tablets of Suzuki et al., as recognized by the Examiner in parent application Serial No. 09/144,827. Thus, the Suzuki et al. patent does not teach each and every element of the claimed invention and therefore does not anticipate the claimed invention. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe the application is in condition for allowance. In view of the above remarks, Applicants respectfully request the Examiner to withdraw all remaining rejections and allow this application.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to

charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 359872000821. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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